

1 percent or less of the acceptable daily intake for these substances.

To determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes the following components: (1) the chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption

from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use. We use this information to determine whether the food-contact substance meets the threshold criteria.

Description of Respondents:
Respondents to this information

collection are individual manufacturers and suppliers of substances used in food-contact articles (*i.e.*, food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of April 7, 2022 (87 FR 20433), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR 170.39	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Threshold of regulation for substances used in food-contact articles	7	1	7	48	336

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The threshold of regulation process offers one advantage over the premarket notification process for food-contact substances established by section 409(h) of the FD&C Act (OMB control number 0910-0495) in that the use of a substance exempted by FDA is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (*e.g.*, use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both Agency and the regulated industry would be significantly less in that other manufacturers and suppliers would not have to prepare, and we would not have to review, similar submissions for identical components of food-contact articles used under identical conditions.

Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Dockets Management Staff and on the internet at <https://www.fda.gov/food/packaging-food-contact-substances-fcs/threshold-regulation-exemptions-substances-used-food-contact-articles>. Having the list of exempted substances publicly available decreases the likelihood that a company would submit a food additive petition or a notification for the same type of food-contact application of a substance for which the Agency has previously granted an exemption from the food additive listing regulation requirement.

Based on a review of the information collection since our last request for

OMB approval, we have made no adjustments to our burden estimate.

Dated: November 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-24801 Filed 11-14-22; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Secretary's Advisory Council on Blood Stem Cell Transplantation (ACBSCT) has scheduled public meetings. Information about ACBSCT and the agenda for these meetings can be found on the ACBSCT website at <https://bloodstemcell.hrsa.gov/about/advisory-council>.

DATES:

- Monday, December 5, 2022, 12–4 p.m. Eastern Time; and
- Tuesday, December 6, 2022, 12–4 p.m. Eastern Time.

ADDRESSES: This meeting will be held virtually by webinar. A link to register and join the meeting will be posted at least 10 days prior to the meeting at <https://bloodstemcell.hrsa.gov/about/advisory-council>.

FOR FURTHER INFORMATION CONTACT:

Shelley Grant, Designated Federal Official, at the HRSA's Health Systems Bureau, Division of Transplantation, 5600 Fishers Lane, 8W-67, Rockville, Maryland 20857; 301-443-8036; or ACBSCTHRSA@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACBSCT provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on policy, program development, and other matters of significance concerning the activities under the authority of 42 U.S.C. Section 274k, Section 379 of the Public Health Service Act, as amended, and Public Law 109-129, and as amended.

During the December 5 and December 6, 2022, meetings, ACBSCT will discuss the impact of COVID-19 on blood stem cell donation and transplantation; unmet needs in blood stem cell transplantation and cellular therapy; strategies to improve rates of adult blood stem donation; and other areas to increase blood stem cell donation and transplantation. Agenda items are subject to change as priorities dictate. Refer to the ACBSCT website for any updated information concerning the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings; oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACBSCT should be sent to Shelley Grant using the contact information above at least 3 business days prior to the meeting. Individuals who plan to

attend and need special assistance or another reasonable accommodation should notify ACBSCT at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022-24788 Filed 11-14-22; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice for Public Comments on Healthcare-Associated Infections (HAI) National Action Plan Targets

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice for public comment.

SUMMARY: The Department of Health and Human Services' (HHS) Office of Infectious Disease and HIV/AIDS Policy (OIDP) in the Office of the Assistant Secretary for Health (OASH) announces the draft targets for updating the Healthcare-Associated Infections (HAI) National Action Plan, Phase 1, Acute Care Hospitals, for public comment. The HHS Core Group of the HAI National Action Plan reviewed data pre-pandemic and between 2020 and 2021 and developed potential 5-year targets based on assumptions that current HAI rates should return to pre-pandemic baseline rates within 2 years or within 3 years when determining these 5-year targets. The HHS HAI NAP Core Group recommends 5-year targets assuming a return to pre-pandemic baseline rates within 3 years based on two fundamentals: (1) pandemic-related challenges will likely persist in upcoming years, and (2) the pandemic has caused major strains on the health care system which make a 3-year timeline to achieve pre-pandemic Standardized Infection Ratio (SIR) the most appropriate choice. The draft targets are below.

DATES: All comments must be received by 5:00 p.m. ET on January 13, 2023, to be considered.

ADDRESSES: All comments must be submitted electronically to OIDP-HAI@hhs.gov to be considered.

FOR FURTHER INFORMATION CONTACT: Chinedu R. Okeke, OIDP, Medical Officer at chinedu.okeke@hhs.gov or 202-868-8872.

SUPPLEMENTARY INFORMATION: Healthcare Associated Infections (HAIs) are

infections that patients get while receiving care or treatment, and many HAIs are preventable. Modern healthcare employs many types of invasive devices and procedures to treat patients and to help them recover. Infections can be associated with surgeries and the devices used in medical procedures, such as catheters or ventilators and due to the transmission of pathogens. HAIs are an important cause of morbidity and mortality in the United States and are associated with a substantial increase in healthcare costs each year. At any given time in the US, 1 out of every 31 hospitalized patients are affected by an HAI. HAIs occur in all types of care settings, including acute care hospitals, ambulatory surgical centers, dialysis facilities, outpatient care, and long-term care facilities. The updates here are for phase 1 of the action plan, which focuses on acute care hospitals.

HAIs are a significant source of complications across the continuum of care and can be transmitted between different healthcare facilities. However, recent studies suggest that implementing existing prevention practices can lead up to a 70 percent reduction in certain HAIs. Likewise, recent modeling data suggests that substantial reductions in resistant bacteria, like MRSA, can be achieved through coordinated activities between healthcare facilities in each region. The financial benefit of using these prevention practices is estimated to be \$25 billion to \$31.5 billion in medical cost savings. Risk factors for HAIs can be grouped into three general categories: medical procedures and antibiotic use, organizational factors, including risks for pathogen transmission, and patient characteristics. The behaviors of health care providers and their interactions with the health care system also influence the rate of HAIs.

To provide a roadmap for HAI prevention, HHS released the National Action Plan to Prevent Health Care-Associated Infections: Roadmap to Elimination (HAI National Action Plan) in 2009 with updates to phase 1, acute care hospitals made in 2013 and 2018. In 2020, HHS leadership transitioned the HAI portfolio to the Office of Infectious Disease and HIV/AIDS Policy (OIDP). To date, OIDP is the lead for the federal steering committee and charged with leading the process to update the HAI National Action Plan. Due to the COVID-19 pandemic, HHS and implementing agencies delayed the process of updating the national action plan and indicator targets for HAIs in acute care hospitals due to data instability. This proposed update would

include new indicator targets for certain HAIs in acute care hospitals.

Goals

All Goals Are Five-Year Goals With the Baseline Year Being 2023 and the Goal Year Being 2028

- Reduce central line-associated bloodstream infections (CLABSI) in intensive care units and ward-located patients by 40% from 2023–2028
- Reduce catheter-associated urinary tracts infections (CAUTI) in intensive care units and ward-located patients by 25% from 2023–2028
- Reduce hospital-onset MRSA bacteremia by 40% from 2023–2028
- Reduce hospital-onset *Clostridioides difficile* infections (CDI) by 20% from 2023–2028

Of note, the previous iteration of the HAI national action plan included targets for reducing surgical site infections (SSI). However, during the period of 2020–2022, there has been significant data instability for SSI due to variable surgical volume related to deferral of elective surgeries in hospitals undergoing COVID surges. The HAI national action plan Core Group therefore decided not to establish targets for SSI at this time.

Information Needs

HHS seeks to obtain feedback from external stakeholders on the following:

1. Are the draft targets realistic and achievable?
2. Are there any critical gaps in the draft targets? If so, please specify the gaps.
3. Do you have any concerns about the targets? If so, please specify, and describe the concern regarding it.

Each commenter is limited to a maximum of seven pages.

Dated: November 2, 2022,

B. Kaye Hayes,

Deputy Assistant Secretary for Infectious Disease, Director, Office of Infectious Disease and HIV/AIDS Policy, Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2022-24822 Filed 11-14-22; 8:45 am]

BILLING CODE 4150-44-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as